

**REMARKS**

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the remarks and amendments herein.

**I. THE OBJECTION TO THE SPECIFICATION IS OVERCOME**

The specification was objected to because of informalities present in the paragraph describing related applications. Applicants respectfully submit that the amendment herewith renders the objection moot. Consequently, reconsideration and withdrawal of the objection to the specification is respectfully requested.

**II. THE ART REJECTIONS ARE OVERCOME**

Claims 15 and 21 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Tartaglia et al. (U.S. Patent No. 5,990,091) in view of Molitor et al. (1985). Claims 15, 21, 24 and 25 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Tartaglia et al. in view of Molitor et al. and Olsen et al. (1997). Claims 15, 21, 24, 25, 26 and 27 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Tartaglia et al. in view of Molitor et al. and Olsen et al., in further view of Cochran et al. (U.S. Patent 5,731,188). And, claims 15, 21, 24, 25, 26, 27 and 28 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Tartaglia et al., Molitor et al., Olsen et al., and Cochran et al., in further view of Oxburgh et al. (1998). Applicants respectfully traverse the rejections and will address the rejections collectively.

Establishing a *prima facie* case of obviousness requires that the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP 2143.

The Examiner is respectfully reminded of the case law, namely, that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). As stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): “The mere fact that the prior art may be modified in the manner suggested by the Office Action does not make the modification obvious unless the prior art suggests the desirability of the modification.” Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, both the suggestion of the claimed

invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). Furthermore, the Supreme Court has recently reaffirmed the factors set out in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18: “[T]he scope and content of the prior art are determined; differences between the prior art and the claims at issue are...ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_\_ (2007).

Applicants respectfully submit that none of the cited references render obvious the present invention.

Each of the obviousness rejections relies initially upon Tartaglia for the teaching of the use of canarypox vectors, the use of at least one vector, the encoding of an equine influenza antigen, as well as at least one heterologous gene or multiple genes, and the use of an adjuvant. Office Action at 4.

Initially, Applicants respectfully assert that one cannot extrapolate from Tartaglia to arrive at the instant claims as each of the locations in Tartaglia cited in the Office Action are portions of “laundry lists” of components and potential features of a vector and/or composition. There is no guidance provided that would enable one of skill in the art to select from the laundry lists only those components utilized in the present claims.

Further, the present claims require that a “single dose” of the vaccine composition “provides immunity against influenza virus”. That the present invention results in immunity following a single dose of the vaccine composition is an unexpected result that is not taught or suggested by any of the cited references. No such teaching or suggestion of these unexpected results is provided in Tartaglia or any of the other cited references. Thus, the cited references, in any combination, fail to teach or suggest each and every element of the claims.

Thus, the cited references, and Tartaglia in particular, fail to render obvious the present claims, and none of the remaining documents remedy the deficiencies of Tartaglia. As Tartaglia is utilized in the Office Action as the main reference in each of the obviousness rejections, the present showing that one would not select elements of the present invention from the laundry

lists in Tartaglia, and that Tartaglia fails to teach or suggest the conveyance of immunity by a single dose of a vaccine composition, neither of which are remedied by the remaining documents, necessitates that all of the rejections be withdrawn.

In addition, Applicants also note that one of skill in the art would not combine the references as provided in the Office Action. Molitor relates to diseases of porcines in guinea pigs, and Olsen provides data using only mice. One of skill in the art would not extrapolate from such varied species with any expectation of success, let alone an expectation of conferring immunity with a single dose of a vaccine composition.

Therefore, the present rejections are improper and must be withdrawn. Consequently, due to all of the reasons set forth above, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103 is respectfully requested.

### **III. THE DOUBLE PATENTING REJECTIONS ARE OVERCOME**

Claims 15, 21, 24, 25, 26, 27 and 28 were rejected under 35 U.S.C. §101 as allegedly claiming the same invention as that of claims 1, 2, 8, 14, 15, 16 and 17 of U.S. Patent 6,713,068. The rejection is respectfully traversed.

The present claims require that a “single dose” of the vaccine composition “provides immunity against influenza virus”. Such a limitation is not present in the claims of the ‘068 patent, and such a limitation renders the present claims patentable over those of the ‘068 patent. Further, it is respectfully noted that as the recitation is not present in the preamble of the pending claims, weight must be given to the limitation.

“Immunity” requires that the vaccine composition protect against challenge. In the instant case, this must be provided via a single dose of the claimed composition. By contrast, all of the examples in the ‘068 patent which describe challenge results utilized protocols wherein at least two separate doses of the vaccine composition were given to the subjects. Thus, one of skill in the art reading the ‘068 patent would not expect that immunity could be obtained after only a single dose of a vaccine composition, such that the present application demonstrates surprising and unexpected results in comparison to the ‘068 patent. Accordingly, the present claims are patentable over those of the ‘068 patent in view of the unexpected results.

Claims 15, 24 and 26 were rejected under the doctrine of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1, 5, 6, 7 and 8 of U.S. Patent No. 6,558,674 in view of Molitor et al. The rejection is respectfully traversed.

As described above, the present claims require that a “single dose” of the vaccine composition “provides immunity against influenza virus”. No such limitation is present in the claims of the ‘674 patent, and such a limitation renders the present claims patentable over those of the ‘674 patent. Indeed, the ‘674 patent does not contain any challenge results at all, let alone any disclosure that a single dose of a vaccine composition, could result in immunity. Thus, the present application demonstrates surprising and unexpected results in comparison to the ‘674 patent. And, the citation to Molitor does not remedy this deficiency in the ‘674 patent. Accordingly, the present claims are patentable over those of the ‘674 patent, either alone or in combination with Molitor, in view of the unexpected results.

Therefore, reconsideration and withdrawal of the double patenting rejections are respectfully requested.

#### **REQUEST FOR INTERVIEW**

If any issue remains as an impediment to allowance, an interview with the Examiner is respectfully requested prior to issuance of any paper other than a Notice of Allowance. The Examiner is additionally respectfully requested to telephonically contact the undersigned to arrange a mutually convenient time and manner for the interview.

#### **CONCLUSION**

In view of these amendments and remarks, the application is in condition for allowance. Early and favorable reconsideration of the application, reconsideration and withdrawal of the objections and rejections, and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,  
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